CONGRESSIONAL BUDGET OFFICE
COST ESTIMATE

May 15, 2003

S. 313
Animal Drug User Fee Act of 2003

As ordered reported by the Senate Committee on Health, Education, Labor, and Pensions on February 12, 2003

SUMMARY

S. 313 would amend the Federal Food, Drug, and Cosmetic Act to authorize the Food and Drug Administration (FDA) to collect fees to cover the cost of expediting the review of new and supplemental animal drug applications and investigational animal drug submissions. Such fees could be collected and made available for obligation only to the extent, and in the amount, provided in advance in appropriation acts.

S. 313 also would require that the Secretary of Health and Human Services submit annual performance and fiscal reports related to the animal drug user fee program to the Congressional committees of jurisdiction.

CBO estimates that implementing S. 313 would reduce net outlays by $1 million in 2004 and $4 million over the 2004-2008 period, assuming the necessary authorities are provided in appropriation acts.

S. 313 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would not affect the budgets of state, local, or tribal governments.

The bill would impose private-sector mandates as defined in UMRA on manufacturers of new animal drugs, by requiring them to pay fees to the Food and Drug Administration. CBO estimates that the direct cost of the mandates would not exceed the annual threshold specified in UMRA ($117 million in 2003, adjusted annually for inflation) in any of the first five years that the mandates would be effective.

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated budgetary impact of S. 313 is shown in the following table and assumes enactment of the bill by October 1, 2003. The costs of this legislation fall within budget function 550 (health).

	By Fiscal Year, in Millions of Dollars					
	2003	2004	2005	2006	2007	2008
CHANGES IN SPENDING SUBJECT TO APPROPRIATION: FOOD AND DRUG ADMINISTRATION						
Collection of User Fees						
Estimated Authorization Level	0	-5	-8	-11	-11	-14
Estimated Outlays	0	-5	-8	-11	-11	-14
Spending of User Fees						
Estimated Authorization Level	0	5	8	11	11	11
Estimated Outlays	0	3	7	10	10	11
Administrative Expenses						
Estimated Authorization Level	0	1	*	*	*	1
Estimated Outlays	0	1	*	*	*	1
Net Effect on Spending by the Food and Drug Administration						
Estimated Authorization Level	0	1	*	*	*	-2
Estimated Outlays	0	-1	*	*	*	-2

Note: * = Less than $500,000.

BASIS OF ESTIMATE

Estimated Authorizations

S. 313 would establish a new user fee program to help defray FDA's costs of expediting the review process for animal drugs. CBO estimates that implementing the bill would save $1 million in 2004 and $4 million over the 2004-2008 period.

User Fees. S. 313 would require FDA to assess and collect application and other user fees from manufacturers of drugs for animals to expedite the development of such drugs and the

review of new and supplemental animal drug applications and investigational animal drug submissions. S. 313 would create four types of user fees: (1) animal drug application and supplement fees, (2) animal drug product fees, (3) animal drug establishment fees, and (4) animal drug sponsor fees. The fees could be refunded, waived, or reduced in certain situations. The aggregate amounts of such fees are specified for each fiscal year 2004 through 2008. Each year the amounts to be collected would be adjusted further for inflation, workload estimates, and other factors, when applicable. CBO assumes FDA would collect the amounts specified in the bill increased by the inflation index for wages and salaries for federal workers. In total, we estimate receipts from those fees would amount to $48 million over the 2004-2008 period. Such fees could be collected and made available for obligation only to the extent, and in the amount, provided in advance in appropriation acts.

Under the bill, those user fees could not be assessed in a given year unless appropriations for salaries and expenses of FDA (excluding the amount of user fees appropriated for such fiscal year) in that year satisfy a maintenance-of-effort requirement: the amount appropriated would have to exceed the amount appropriated for 2003 by the percentage increase since 2003 in the consumer price index for all urban consumers (CPI-U). In addition, fees could be collected and made available to defray increases in the cost of resources allocated to reviewing animal drug applications only to the extent that the percentage increase in those costs (excluding fees) exceeds the costs for fiscal year 2003 adjusted by CPI-U. (The bill defines special circumstances under which the Secretary would be considered to have met the maintenance-of-effort requirement.) This estimate assumes that these conditions would be met.

Before accounting for costs associated with additional administrative activities not covered by the user fees, CBO estimates that establishing the user fee program would reduce net outlays by $2 million in 2004 and $7 million over the 2004-2008 period, assuming appropriation of the necessary amounts. The estimated budget authority for collections and spending offset each other exactly from 2004 through 2007, while outlays would lag slightly, resulting in small savings each year. For fiscal year 2008, the bill would authorize the assessment and collection of up to three months of operating reserves for the review of animal drug applications for the first three months of fiscal year 2009. However, the user fee program is authorized only through fiscal year 2008. CBO assumes that the amounts available for obligation and spending in fiscal year 2008 would not include those special reserve funds collected in that year. The difference between the estimated collections and spending of the user fees in fiscal year 2008 would result in savings of $3 million for that year, CBO estimates.

Other Administrative Expenses. Based on the experience with similar activities of FDA, CBO assumes that funding for certain administrative activities associated with the new user fee program would not be fully covered by the new fees. The bill would require that FDA report annually to the Congress on its performance under the user fee program and on the

fiscal status of the program. S. 313 also would require that FDA consult with the Congressional committees of jurisdiction and outside experts, including industry and consumer groups, and publish its recommendations concerning reauthorization of the user fee program. CBO estimates that the administrative activities associated with implementing the user fee program that are not covered by the user fees would cost about $2 million over the 2004-2008 period.

ESTIMATED IMPACT ON STATE, LOCAL AND TRIBAL GOVERNMENTS

S. 313 contains no intergovernmental mandates as defined in UMRA and would not affect the budgets of state, local, or tribal governments.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

Subject to approval in an appropriation act, S. 313 would require manufacturers of new drugs for animals to pay application fees, product fees, establishment fees, and drug-sponsor fees to FDA. The application fees would apply to new or supplemental animal drug applications that are submitted after September 1, 2003. The product, establishment and drug sponsor fees would apply to manufacturers of new animal drug products that have an application pending with FDA after September 1, 2003. The duty to pay those fees would be a private-sector mandate under UMRA. CBO estimates that the fees collected over the 2004-2008 period would total $48 million. Those amounts would not exceed the annual threshold specified in UMRA ($117 million in 2003, adjusted annually for inflation) in any of the first five years that the mandates would be effective.

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